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C. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

[in Accordance with SMDA of 1990]

RESTERILIZATION OF YASARGIL PERMANENT ANEURYSM CLIPS

November 3, 2000

COMPANY: Aesculap®, Inc.
944 Marcon Blvd.
Allentown, PA 18109

CONTACT: Joyce Thomas, Director Regulatory Affairs & Quality Assurance
800/258-1946 x 5074 (phone)
610/231-3713 (fax)

TRADE NAME: Yasargil Permanent Aneurysm Clips

COMMON NAME: Aneurysm Clips

DEVICE CLASS: Class II

PRODUCT CODE: 84 HCH

CLASSIFICATION: 21 CFR Section 882.5200 – Clip, Aneurysm

REVIEW PANEL: Neurology
Division of General, Restorative, and Neurological Devices

INDICATIONS FOR USE

The Yasargil Permanent Aneurysm Clips are intended for occlusion of cerebral aneurysms in a permanent manner. They are applied with Aesculap clip appliers, which contain titanium alloy or phynox jaws.

DEVICE DESCRIPTION

The Yasargil Permanent Aneurysm Clips are manufactured from either titanium alloy, Ti6Al4V (according to ISO 5832/3) or phynox cobalt alloy (according to ISO 532/7) – both of which are non-ferromagnetic and MR compatible. The clips range in size from 2.8mm to 20mm blade length with a maximum blade opening from 3.2mm to 11.4mm, and are available in straight, curved, angled, bayonet, fenestrated, and non-fenestrated styles.

PURPOSE FOR SUBMISSION

There have been no design modifications to the existing Yasargil Permanent Aneurysm Clips; the sole purpose for this submission is to gain marketing clearance for the resterilization of the permanent titanium and phynox clips. Test data demonstrated that repeated sterilization did not adversely affect the closing force of the clips.

PERFORMANCE DATA

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for this device system. Aesculap's Yasargil Aneurysm Clips, however, are manufactured and labeled according to applicable ASTM and ISO Standards.

SUBSTANTIAL EQUIVALENCE

The resterilization instructions described in this premarket notification are substantially equivalent to the following predicate devices: Spetzler Titanium Aneurysm Clips (K955064) and Sugita Titanium and Elgiloy Aneurysm Clips (K990202, K960372).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 9 2001

Ms. Joyce Thomas
Director, Regulatory Affairs/Quality Assurance
Aesculap, Inc.
944 Marcon Boulevard
Allentown, Pennsylvania 18109

Re: K003519
Trade Name: Yasargil Permanent Aneurysm Clips
Regulatory Class: II
Product Code: HCH
Dated: November 3, 2000
Received: November 15, 2000

Dear Ms. Thomas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE STATEMENT

510(k) Number: K003519

Device Name: **Resterilization of Yasargil Permanent Aneurysm Clips**

Indication for Use:

The Yasargil Permanent Aneurysm Clips are intended for occlusion of cerebral aneurysms in a permanent manner. They are applied with Aesculap clip appliers, which contain titanium alloy or phynox jaws.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003519

Prescription Use X or Over-the-Counter Use _____

(per 21 CFR 801.109)

(Optional Format 3-10-98)